CLAIMS

1. A pharmaceutical aerosol formulation for use in a metered dose inhaler (MDI) comprising formoterol fumarate di-hydrate in suspension, a propellant and ethanol, wherein the formoterol fumarate di-hydrate is provided having a water content of about 4.8 to 4.28% by weight.

2. A pharmaceutical aerosol formulation according to claim 1 comprising formoterol fumarate di-hydrate in suspension, and a steroid in solution, a propellant and ethanol, wherein the formoterol fumarate di-hydrate is provided having a water content of about 4.8 to 4.28% by weight.

3. A pharmaceutical aerosol suspension formulation according to claim 1 or claim 2 comprising formoterol fumarate di-hydrate in suspension, and a steroid in solution, a propellant and ethanol, wherein the formoterol fumarate di-hydrate is provided having a water content of about 4.8 to 4.28% by weight, and wherein the formulation is capable of being dispensed from an MDI to provide an Delivered dose of formoterol fumarate di-hydrate that has a variance of no more than +/- 25%, of the mean Delivered dose when the formulation is stored at 40°C and 75% relative humidity for up to 6 months.

4. A pharmaceutical aerosol suspension formulation according to any preceding claim comprising formoterol fumarate di-hydrate in suspension, and a steroid in solution, a propellant and ethanol, wherein the formoterol fumarate di-hydrate has a water content of about 4.8 to 4.28% by weight, wherein the formulation is capable of being dispensed from an MDI to provide an Delivered dose of formoterol fumarate di-hydrate with a fine particle fraction of 30 to 70%.

5. A pharmaceutical aerosol suspension formulation according to any of the preceding claims comprising formoterol fumarate di-hydrate in suspension, and a steroid in solution, a propellant and ethanol, wherein the formoterol fumarate di-hydrate is provided as particles having a water content of about 4.8 to 4.28% by weight

suspended in the propellant and solvent, and wherein the formulation is capable of being dispensed from an MDI to provide a Delivered dose of the steroid that has a variance of no more than +/- 25%, of the mean Delivered dose when the formulation is stored at, 40°C and 75% relative humidity for up to 6 months.

6. A pharmaceutical aerosol suspension formulation according to any of the preceding claims comprising formoterol fumarate di-hydrate in suspension, and a steroid in solution, a propellant and ethanol, wherein the formoterol fumarate di-hydrate has a water content of about 4.8 to 4.28% by weight, and wherein the formulation is capable of being dispensed from an MDI to provide a Delivered dose of steroid containing a fine particle fraction of 30% to 70%.

7. A formulation according to any of the preceding claims wherein the steroid is selected from the group consisting of budesonide, ciclesonide, mometasone, fluticasone, beclomethasone, flunisolide, loteprednol, triamcinolone, amiloride, rofleponide or a pharmaceutically acceptable salt or derivative of these active compounds, selected from mometasone furoate, fluticasone dipropionate, beclomethasone dipropionate, triamcinolone acetonide or flunisolide acetate.

8. A formulation according to claim 7 wherein the steroid is ciclesonide.

9. A formulation according to claim 8 wherein the ciclesonide is present in an amount of 0.05 to 2 % by weight of the formulation.

10. A formulation according to any of the preceding claims wherein the formoterol fumarate di-hydrate is present in an amount of 0.001 to 0.1% by weight of the formulation.

11. A formulation according to according to any of the preceding claims containing a cromone selected from the group consisting of a pharmaceutically acceptable salt of cromoglycinic acid, nedocromil, or mixtures thereof.

12. A formulation according to claim 11 wherein the cromone is present in the formulation in an amount of 0.001 to 1%.

13. A formulation according to any of the preceding claims wherein the propellant is selected from the group consisting of example fluorochlorocarbons such as trichloro-monofluoromethane (F11), dichlorodifluoromethane (F12), monochlorotrifluoromethane (F13), dichloro-monofluoromethane (F21), monochlorodifluoromethane (F22), monochloromonofluoromethane (F31), 1,1,2-trichloro-1,2,2-trifluoroethane (F113), 1,2-dichloro-1,1,2,2-tetrafluoroethane (F114), 1-chloro-1,1,2,2,2-pentafluoroethane (F115), 2,2-dichloro-1,1,1-trifluoroethane (F123), 1,2-dichloro-1,1,2-trifluoroethane (F123a), 2-chloro-1,1,1,2-tetrafluoroethane (F124), 2-chloro-1,1,2,2-tetrafluoroethane (F124a), 1,2-dichloro-1,1-difluoroethane (F132b), 1-chloro-1,2,2-trifluoroethane (F133), 2-chloro-1,1,1-trifluoroethane (F133a), 1,1-dichloro-1-fluoroethane (F141b) and 1-chloro-1,1-difluoroethane (F142b), alkanes such as propane, butane and isobutane, fluorinated alkanes such as octafluoropropane (F218) and in particular hydrofluoroalkanes such as difluoromethane (HFA 32), pentafluoroethane (HFA 125), 1,1,2,2-tetrafluoroethane (HFA 134), 1,1,1,2-tetrafluoroethane (HFA 134a), 1,1,2-trifluoroethane (HFA 143), 1,1,1-trifluoroethane (HFA 143a), difluoroethane (HFA 152a), or 1,1,1,2,3,3,3-heptafluoropropane (HFA 227).

14. A formulation according to claim 13 wherein the propellant is a hydrofluoroalkane of the general formula.

CxHyFz (I)

in which x is the number 1, 2 or 3, y and z are each an integer >==1 and y+z=2x+2.

15. A formulation according to claim 13 or claim 14 wherein the propellant is HFA 134a or HFA 227 or a mixture thereof.

16. A formulation according to any of the preceding claims wherein the propellant is employed in an amount of greater than 90% by weight.

17. A formulation according to any of the preceding claims wherein the ethanol is present in amounts of 1% to 8% by weight.

18. A formulation according to any of the claims comprising a surfactant selected from the group consisting of oleic acid, lecithin, sorbitan trioleate, cetylpyridinium chloride, benzalkonium chloride, polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (20) sorbitan monooleate, polyoxypropylene/polyoxyethylene block copolymers, polyoxypropylene/polyoxyethylene/ethylenediamine block copolymers, and ethoxylated castor oil

19. A formulation according to claim 18 wherein the surfactant is present in an amount of 0.0001 to 1% by weight.

20. A pharmaceutical aerosol formulation for use in a metered dose inhaler (MDI) comprising formoterol fumarate di-hydrate in suspension, a propellant and ethanol, wherein the moisture content of the formulation is in the range of from 50 ppm to 800 ppm.

21. A vial containing a formulation as defined in any of the preceding claims.

22. A vial according to claim 21 in the form of an aluminium, uncoated container.

23. A vial according to claim 21 or claim 22 adapted to be placed in a metered dose inhaler, and capable of delivering a dosage of formoterol fumarate di-hydrate of about 3 to 15 micro-grams.

24. A vial according to claim 21 to 23 adapted to be placed in a metered dose inhaler, and capable of delivering a dosage of a steroid of about 10 to 1000 micro-grams per puff.

25. A vial according to claim 24 adapted to be placed in a metered dose inhaler, and, capable of delivering a dosage of ciclesonide of about 50 to 500 micro-grams per puff.

26. A package comprising a vial as defined in claim 21 or claim 22 containing a formulation as defined in any of the preceding claims, and a label containing a dosage claim, wherein the mean Delivered dose of the active substances is no more than +/- 15% of the dosage contained stated in the label.

27. A metered dose inhaler containing a vial as defined in any of the claims 21 to 25.

28. A method of producing a pharmaceutical aerosol formulation or a vial as defined in any of the claims 1 to 25 comprising the step of drying the formoterol fumarate di-hydrate to a water content of 4.8 to 4.28%.